



Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

792-A-PCT-US

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EV 766835044 US

Albert Wai-Kit Chan 5/18/06
Albert Wai-Kit Chan Date
Reg. No. 36,479

Application Number

10/650,365

Filed

August 28, 2003

First Named Inventor

Guangwen WEI

Art Unit

1647

Examiner

Jegatheesan Seharaseyon

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal. See Exhibit A for a copy of the Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

See Exhibit B for Applicants' reasons for requesting a pre-appeal brief review.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. **36,479**
Registration number

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34

Albert Wai-Kit Chan
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May 18, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Wei et al.
U.S. Serial No. : 10/650,365
Filing Date : August 28, 2003
Examiner : Jegatheesan Seharaseyon
Art Unit : 1647
For : RECOMBINANT SUPER-COMPOUND INTERFERON

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May 18, 2006

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW PURSUANT TO JULY 12, 2005
PATENT OFFICIAL GAZETTE**

Sir:

This Request is submitted in response to the March 20, 2006 Final Office Action and May 11, 2006 Advisory Action issued by the United States Patent and Trademark Office (USPTO) in connection with the above-identified application. A shortened statutory period for reply is set to expire three (3) months from the mailing date of the Final Office Action, which falls on June 20, 2006. Accordingly, this Request is being timely filed.

REMARKS

I. Pending Claims

Claims 29-37 are pending in this Application. *See* Applicant's response to Office Action filed November 28, 2005 for a copy of the pending claims.

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II. Request to Withdraw the Finality of the Rejection

Applicants respectfully request the Examiner to withdraw the finality of the Final Office Action mailed March 20, 2006 because an aspect of the present invention is not met by the reference cited by the Examiner, and the Examiner has failed to show proper motivation for making a modification in an obviousness rejection.

III. Claim Rejections Under 35 USC § 102(b)

The Examiner rejected claims 29-31 and 34-36 under 35 U.S.C. 102(b) as being anticipated by Day et al. (1992). The Examiner stated that Day et al. teach changing amino acids at positions 17, 29, and 136 of murine interferon- β . *See* Office Action mailed Aug. 23, 2005, page 6. More specifically, Day et al. teach changing Asn-29 and Tyr-136 to cysteines, and changing Cys-17 to serine. *See* Day et al., p.141, left column, third paragraph. Therefore, Day et al. teach the making of an interferon molecule that has a sequence different from that of a wild-type interferon molecule.

In contrast, the present invention provides a recombinant interferon (designated as IFN-con in the amendment filed April 12, 2006) having a sequence identical to a consensus sequence but nevertheless exhibits different biological activities. *See* specification, p.1, ll. 25-27; p.6, ll. 5-12. Through genetic engineering, the present invention changes the cDNA sequence encoding a consensus interferon according to the codon preference of *E. coli*. Consequently, only the codon sequence is changed, but the amino acid sequence of the resulting gene product is not changed. *See* specification, p.7, ll. 6-9; p.19, ll. 14-28. Interestingly, although the interferon of the present invention (IFN-con) maintains the same consensus amino acid sequence, the resulting IFN-con exhibits enhanced or different biological activities as compared to another interferon such as INFERGEN[®] with the same amino acid sequence. *See* specification, p.33, ll. 6-17.

In the amendments filed November 28, 2005, claim 29 recites a recombinant interferon with SEQ ID NO.1. Applicants submit that there is a typographical error on the SEQ ID NO. The correct amino acid sequence ID should be SEQ ID NO.2, whereas SEQ ID NO.1 is the corresponding

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nucleotide sequence. *See* the amended description for Figure 1 filed November 28, 2005. As discussed above, the resulting amino acid sequence is the same as that of a consensus sequence.

In view of the above remarks, Applicants submit that Day et al. only teach the making of an interferon molecule that has a mutated sequence. Day et al. do not teach or suggest an interferon with a consensus sequence but exhibits different or enhanced biological properties as described and claimed herein. Since Day et al. do not teach or suggest each and every aspect of the present invention, Day et al. do not anticipate claims 29-37 of the present invention. Accordingly, Applicants respectfully request that the rejection of claims 29-31 and 34-36 under 35 U.S.C. 102(b) be withdrawn.

IV Claim Rejections Under 35 USC § 103

The Examiner rejected claims 32 and 37 under 35 U.S.C. 103 as being unpatentable over Day et al. (1992) in view of Olsen et al. (US Patent No. 6,114,145) and Nasoff et al. (1999).

As discussed above, the primary reference Day et al. do not teach or suggest an interferon with a consensus sequence but exhibits different or enhanced biological properties as described and claimed herein. Neither Olsen et al. nor Nasoff et al. was cited to provide teaching for such aspect of the present invention. *See* Office Action mailed Aug. 23, 2005, page 7. Therefore, combining Day et al. with Olsen et al. and Nasoff et al. would not lead to each and every aspect of the present invention, and the present invention is not obvious in view of the cited references. Accordingly, Applicants respectfully request that the rejection of claims 32 and 37 under 35 U.S.C. 103 be withdrawn.

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Conclusion

Applicants respectfully urge the Examiner to consider the issues discussed in this Request and in Applicants' proposed amendment filed April 12, 2006, and withdraw the finality of the Final Office Action mailed March 20, 2006 and place this Application in condition for allowance.

Respectfully submitted,

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